



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2020-N-0862]**

#### **Captain Neill's Seafood, Inc.: Final Debarment Order**

**AGENCY:** Food and Drug Administration

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Capt. Neill's Seafood, Inc. (Capt. Neill's or the Company) for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Capt. Neill's was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. The Company was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of 30 days after receipt of the notice (July 13, 2020), Capt. Neill's has not responded. Capt. Neill's failure to respond and request a hearing constitutes a waiver of the Company's right to a hearing concerning this matter.

**DATES:** This order is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa (ELEM-4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs,

Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 or at [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2020, Capt. Neill's was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the U.S. District Court for the Eastern District of North Carolina, when the court accepted the Company's plea of guilty and entered judgment against it for the offense of violating the Lacey Act and Aiding and Abetting. This offense was in violation of 16 U.S.C. 3372(d)(1), 3373(d)(3)(A)(i) and (ii), and 18 U.S.C. 2.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Indictment, filed on June 26, 2019, Capt. Neill's is a North Carolina corporation in the business of purchasing, processing, packaging, transporting, and selling seafood and seafood products, including crab meat from domestically harvested Atlantic blue crab, and products made from Atlantic blue crab. From as early as January 1, 2012 and continuing through December 31, 2015, Capt. Neill's purchased foreign crab meat from South American and Asia. Capt. Neill's employees repacked the foreign crab meat into containers labeled "Product of USA." Capt. Neill's employees then knowingly sold those containers of foreign crab meat as jumbo

domestically harvested blue crab to customers. During the relevant time frame, Capt. Neill's sold approximately 200,536 pounds of crab meat falsely labeled "Product of USA" with a total retail market value of \$4,082,841.

As a result of this conviction FDA sent Capt. Neill's, by certified mail on May 6, 2020, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Capt. Neill's felony conviction of violating the Lacey Act and Aiding and Abetting in violation 16 U.S.C. 3372(d)(1), 3373(d)(3)(A)(i) and (ii), and 18 U.S.C 2, constitutes conduct relating to the importation into the United States of an article of food because the offense involved Capt. Neill's employees falsely labeling crabmeat that was imported from foreign countries and purporting that the crabmeat was a "Product of USA."

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Capt. Neill's should be subject to a 5-year period of debarment. The proposal also offered Capt. Neill's an opportunity to request a hearing, providing the Company 30 days from the date of receipt of the letter in which to file the request, and advised Capt. Neill's that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Capt. Neill's failed to respond within the timeframe prescribed by regulation and has, therefore, waived the Company's opportunity for a hearing and waived any contentions concerning Capt. Neill's debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant

Commissioner, finds that Capt. Neill's has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that the Company is subject to a 5-year period of debarment.

As a result of the foregoing finding, Capt. Neill's is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Capt. Neill's Seafood, Inc. is a prohibited act.

Any application by Capt. Neill's for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-0862 and sent to the Dockets Management Staff (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <http://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*